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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cook

Serial No.: 08/877,317 **Group Art Unit: 1633**

Filed: June 17, 1997 **Examiner: J. Martinell**

For: PNA-DNA-PNA CHIMERIC MACROMOLECULES

I, Gregory L. Hillyer, Registration No. 44,154 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On February 2, 2001

Gregory L. Hillyer Reg. No. 44,154

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APPELLANT'S REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193

I. Summary of the Argument on Reply

The Examiner's Answer does not dispute that Appellant's disclosure would be sufficient to enable those skilled in the art to practice the claimed methods to at least some measurable extent. The Examiner nonetheless attempts to justify maintenance of his rejection of the claims for alleged lack of enablement by asserting that Appellant is under an obligation to address all problems that might be associated with optimizing the use of oligonucleotides as therapeutics. Since the patent laws do not require that Applicant meet this onerous standard, the rejection for alleged lack of enablement should be withdrawn.

II. Response To Issues Raised By The Examiner

A. There Is No Dispute That Those Skilled in the Art Would Be Able To Practice the Claimed Methods and Obtain Measurable Results.

The Examiner's Answer fails to dispute that those skilled in the art would be able to achieve a measurable result by contacting a macromolecule having the structure PNA-DNA-PNA with an organism in accordance with claims 13-16, 19, 20, and 24-26. In fact, the Examiner's Answer improperly dismisses several passages of the Rojanasakul reference that support Appellant's position that those skilled in the art would be able to practice the claimed inventions. In so doing, the Examiner's Answer fails to consider the Rojanasakul reference as a whole, as required by law. *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981).

Although the Examiner's Answer criticizes Appellant's disclosure as allegedly failing to address each and every "problem" described in Rojanasakul, *Advanced Drug Delivery Reviews*, 18, 115-131 (1996) ("the Rojanasakul reference"), the Answer does not so much as suggest that these problems would be so great so as to impede practice of the claimed methods. Thus, such methods are enabled within the meaning of 35 U.S.C. §112.

B. There Is No Basis for Requiring the That a Patent Application Optimize the Performance of a Therapeutic Product.

There is no basis for maintenance of the rejection for alleged lack of enablement simply because, in the Examiner's view, § 112 requires that an applicant do more than enable practice of a claimed method. Although the literal language of the present claims requires nothing more than use of recited compounds to achieve measurable results, the Examiner in his Answer

clings to the notion that he is justified in requiring that the specification provide a level of optimization associated only with therapeutic products whose development has progressed to the point of clinical use. That the Examiner's Answer requires the invention to be optimized is evidenced by statements wherein it erroneously presumes that any and all potential problems must be addressed for the pending claims to be patentable:

> Among [the problems] are: uptake of the antisense agent into the cells, stability of the ONs in cells, and specificity of hybridization of the ONs once inside the cells. The instant application does not address these problems or indicate how they may be overcome in the administration of the PNA-DNA-PNA compounds mentioned in the claims.

(Examiner's Answer at page 5). Significantly, neither the case law nor the patent statute supports the Examiner's position that an invention must be optimized to be patentable. To the contrary, the mere existence of problems associated with the claimed inventions does not negate their patentablility. *In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995). There is simply no legal basis for the Examiner's attempt to establish requirements for patentability that are higher than those imposed by law.

C. The Examiner's Criticism of The Specification Does Not Demonstrate Any Failure to Comply with 35 U.S.C. §112

The Examiner's Answer improperly dismisses Appellant's arguments concerning the means used in the specification to provide an enabling disclosure. Although the Examiner contends that the means used to enable practice of the claimed inventions is "not at issue in this record" (Examiner's Answer at 4), the Examiner nonetheless continues to base his rejection of the claims

on the manner in which Appellant has chosen to enable practice of his inventions. The Examiner's Answer, for example, improperly finds fault with the specification because it allegedly describes the administration of antisense agents to organisms in "general terms" (Examiner's Answer at 4). Notwithstanding the Examiner's attempts to dismiss controlling law supporting the proposition that an enabling disclosure can be provided through broad terminology or any other suitable means (*see, e.g.*, Appellant's opening brief at 4), he cites no authority supporting the position that the use of "general terms" demonstrates a deficiency in a specification. In fact, the Examiner's Answer concedes that Appellant's disclosure addresses the administration of antisense agents to organisms in five separate portions of the specification. Accordingly, there is no evidentiary basis for rejection of the claims.

III. Conclusion

The rejection of claims under 35 U.S.C. § 112, first paragraph, should be reversed, as it is undisputed that those skilled in the art would be able to practice the methods recited in these claims.

Respectfully submitted,

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